BRIEF COMMUNICATIONS

TOLERANCE OF A RESORBABLE COLLAGEN-ELASTIN MEMBRANE AS A PERICARDIAL SUBSTITUTE IN ADULT CARDIAC OPERATIONS

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The increasing number of cardiac reoperations has forced the development of pericardial substitutes to avoid pericardial adhesions resulting from the first operation. Experimental studies have investigated the effect of a biodegradable collagen-elastin patch on preservation of the heart anatomy and pericardium regeneration.[1] With this collagen-elastin patch, pericardial adhesions in experimental animals were minimized; separation of the different structures without restriction was allowed, and the visibility of coronary arteries was preserved. The small peptides released during the degradation of the collagen-elastin complex reduce the elastase and collagenase activity and minimize local inflammatory reaction.[1-3] Collagen-elastin resorption occurs simultaneously with the synthesis of a neopericardium, and the patch acts as a scaffold for the growth of mesothelium-like cells.[1,3] However, no clinical experience exists about the tolerance of this collagen-elastin patch in adult cardiac operations.

The present report shows the initial and medium-term results of the tests of tolerance and biocompatibility performed in a series of patients included in the clinical trial performed at the University Hospital of Valladolid.

From December 1995 to April 1997, 25 patients with a mean age 55.6 years (range, 41 to 74 years) who underwent coronary artery bypass grafting received the biodegradable collagen-elastin patch (OVI S A, Martillac, France) as a pericardial substitute. This patch is made of a complex of bovine elastin (Elastin Products Company, Inc, Avensville, Mo) and bovine collagen (Coletica, Lyon, France) reinforced with a resorbable polygycolate mesh. The patch was applied before sternal closure (covering as smoothly as possible the anterior wall of the right ventricle, the right atrium, pulmonary artery, ascending aorta, and grafts) and held in place by interrupted 5-0 monofilament stitches to the edge of the native pericardium. Two drains were placed into the mediastinum, one under the patch and the other into the left pleural cavity. A group of 12 patients with a mean age of 57 years (range, 47 to 75 years) who underwent coronary artery bypass grafting without the use of the collagen-elastin patch were considered as control.

Demographic and clinical data included age, sex, postoperative fever, wound infection, and hospital stay. Biocompatibility tests included peripheral blood examination, serum protein determination, erythrocyte sedimentation rate, plasma reactive c protein, and α_1-antitrypsin. Acoustic properties of the patch and systolic and diastolic function of the heart were studied by transthoracic Doppler echocardiography. Radioisotopic image evaluation of the mediastinum with leukocytes labeled with technetium Tc 99m-hexamethylpropylenamine-oxine was performed. Analytical, structural, and functional explorations were carried out on postoperative day 8 and postoperative months 2 and 6.

No statistically significant differences were observed between groups when demographic, clinical, radioisotopic, or echocardiographic characteristics (Student *t* test) were compared. Transthoracic ultrasound examination showed normal cardiac structures. No significant changes of systolic ventricular function were observed. A normal pattern of diastolic ventricular filling was confirmed in all patients. No significant pericardial effusion could be observed. Radioisotopic studies did not reveal any difference between the 2 groups, suggesting that there is no significant accumulation of leukocytes around the path.

These preliminary clinical results suggest that the collagen-elastin patch shows an excellent tolerance without increasing the postoperative local and systemic inflammatory responses to cardiac surgery. Physical characteristics of the patch did not interfere with the acoustic properties of the heart nor with diastolic or systolic ventricular function.

On the basis of our preliminary clinical experience, the collagen-elastin patch seems to be biocompatible without noticeable secondary effects. To date no patient has required reoperation. However, future studies will give further information on biologic tissue modifications and on interaction between the biodegradable patch and cardiac structures.

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